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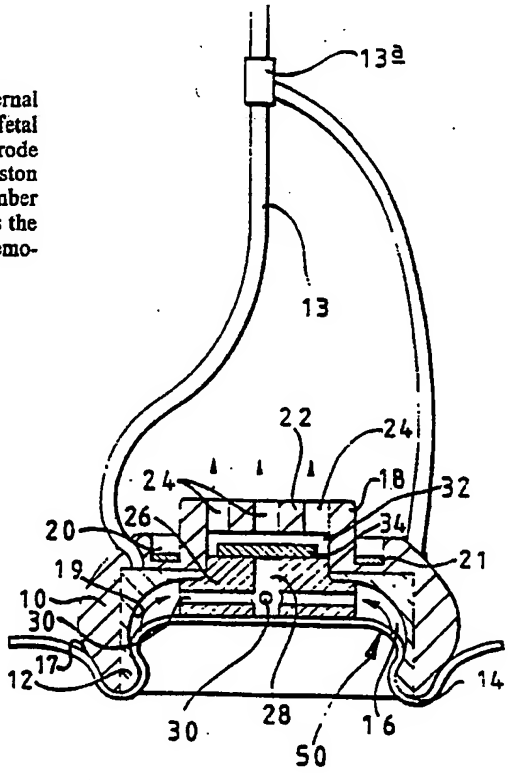
(54) Title: MONITORING DEVICE

(57) Abstract

A fetal monitoring device comprises a cap (10) with internal electrode (12) and recess (16). A sealing edge (14) against which fetal tissue (50) is sealed in use is provided by the cap (10) and electrode (12). A reduced pressure is applied within the recess (16) by a piston (38, 40) and cylinder (36) device through holes (24), valve chamber (32), passage (28) and cross passages (30). A valve disk (34) seals the passage (28) so as to maintain the recess (16) sealed in use after removal of the piston and cylinder device.



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MONITORING DEVICE

This invention relates to a monitoring device and is more particularly concerned with a monitoring device which is to be attached to a fetus for monitoring during labour, eg. for ECG (electrode cardiogram), CTG (cardio-tocography), blood-oxygen level or pH, such device including one or more monitoring elements eg sensors and/or electrodes which are maintained in monitoring contact with the fetus. Whilst the monitoring device of the present invention has been specifically designed to be used for fetal monitoring, it will be appreciated that the device can be used for other monitoring purposes.

Non-invasive fetal monitoring devices are known per se wherein a body of the device is held against the fetal skin by suction. US Patent 4299232 discloses a fetal heart rate monitoring device wherein the body takes the form of a flexible cup which is introduced into the birth canal and initially sealed with the cervix without pressing, and then the device is slid sideways to contact the fetal head and finally pressed to create suction and to cause an electrode inside the flexible cup to pierce the fetal skin. Such an arrangement has the disadvantage that only a relatively limited degree of suction can be applied and there is a risk that the device will become inadvertently detached from the fetal head during labour.

US Patent 4537197 discloses a fetal oxygen monitoring device including a suction cup to hold the distal ends of optical fibres against the fetal skin. The optical fibres are embedded in the wall of a flexible catheter whose distal end is connected to or integral with the suction cup and whose proximal end is connected to a suction syringe to enable a reduced pressure to be applied to the interior of the cup. The piston of the syringe has a catch to engage the cylinder so as to

maintain the reduced pressure in the suction cup. The disadvantage of this type of construction is that the syringe always has to be connected to the suction cup through the flexible catheter and this can impede the person responsible for delivery, particularly as it is present throughout labour and has to be of relatively thick wall construction (a) to withstand the reduced pressure without collapsing or kinking and (b) to contain the optical fibres. Similar problems also apply in the case of the fetal heart beat rate monitor disclosed in British Patent 1260919 where a suction bulb is permanently connected with the device when in use. In WO90/04352, there is disclosed a device having a narrow oblong body fitted with a gasket having a greater compliancy than the fetal tissue surface. The device body has connections for attachment to a vacuum source to enable a partial vacuum to be created within the body and to connect the device to a vent tube. In use, a reduced pressure is continuously applied to the device body, with the vent tube creating a constant flow of air through the device to control the suction pressure and to prevent clogging of the vacuum line. This latter type of device is relatively expensive and complicated in that it requires both a vacuum tube and a vent tube to be connected with the device body continuously during use.

It is an object of the present invention to provide a relatively simple monitoring device which enables the above disadvantages to be obviated or mitigated.

According to the present invention, there is provided a monitoring device comprising a body, a recess within the body, a sealing edge surrounding the recess and adapted to engage sealingly against a surface to which the device is to be secured in use, a passage in the body communicating with the recess, at least one monitoring element carried by the body, and means for applying a

reduced pressure to the passage, and thereby to the recess, so as to secure the body in use to the surface with said at least one monitoring element in a predetermined position relative to said surface, characterized in that the means for applying reduced pressure is detachable from the body, and in that means are provided for sealing said passage so as to enable a reduced pressure to be maintained in the recess in use after detachment of the reduced pressure applying means.

The means for applying reduced pressure may comprise a piston and suction tube device, the suction tube being detachably connected with said passage. In an alternative embodiment, the passage defines the suction tube and the piston itself defines the means for sealing the passage as well as for applying the reduced pressure, the piston being moveable by a mechanism, for example a piston rod and guide tube which are detachable, such arrangement being as described in my British Patent Application No. 9020983.4 filed on 26 September 1990 from which the present application claims priority and in respect of which the disclosure is incorporated herein by reference, as is the disclosure in my British Patent Application No. 9025758.5 filed 27th November 1990.

In the embodiment where the suction tube is detachably engageable with the passage, valve means in the passage provides the means for sealing the latter. Such valve means is preferably a pressure-responsive valve closure member adapted to close when a higher negative pressure exists in the recess than in the reduced pressure applying means.

The body of the monitoring device normally takes the form of a suction cap.

The sealing edge is preferably smooth and convexly curved

and, more preferably, merges with the main part of the outer periphery of the body through the intermediary of a shallow annular concave region. The sealing edge may alternatively, or preferably additionally, merge smoothly with the inner recess via a convex region which merges smoothly with an inner concave region. Such concave region(s) is/are found to reduce the amount of negative pressure required to keep the body in place in use.

The suction tube may comprise an elongate tube which has a vent orifice intermediate its ends arranged so that the tube is vented when the piston has been moved a predetermined distance in a suction-applying direction. With such a construction, it is preferred to arrange for the valve means to close automatically as a result of the differential pressure applied thereacross when the piston has moved past the vent hole in the suction-applying direction.

Said at least one monitoring element may be provided in the region of the sealing edge and, more particularly, may define at least part of the sealing edge. However, it is within the scope of the present invention, and may be preferable in some cases, for said at least one monitoring element to be disposed on the outside of the body, ie away from the area of negative pressure.

In the case where the surface against which the body is to seal is a flexible surface, eg fetal tissue, it is preferred for abutment means to be provided within the recess for limiting deformation of the surface into the recess.

An embodiment of the present invention will be described, by way of example, with reference to the accompanying drawings, in which:-

Fig. 1 is a top plan view of part of a monitoring device according to the present invention,

Fig. 2 is an axial section of the part shown in Fig. 1,

Fig. 3 is an underneath plan view of the part shown in Fig. 1,

Fig. 4 is an axial section through another part of the monitoring device, and

Figs. 5a, 5b and 5c are sections showing the positions in which the valve disk illustrated in Fig. 2 can adopt under various conditions.

Referring now to Figs. 1 to 3 of the drawings, the part of the monitoring device illustrated therein is that which is intended to be anchored to the presenting part of the fetus (usually the fetal head) to secure a CTG pick-up electrode thereto for monitoring of the fetus during labour. The device comprises a body in the form of an electrode cap 10 moulded from an electrically insulating material (eg PVC) and including an internal electrode 12 for CTG monitoring. The electrode 12 is formed of an electrically conductive material (eg stainless steel) and has an insulated electrical lead 13 connected thereto for transmitting signals from the electrode to remote analysis equipment (also not shown). The lead 13 has a stainless steel collar 13a thereon which acts as a reference electrode for contact with the maternal tissue and which is connected via its own lead (also not shown) to the analysis equipment. The cap 10 and electrode 12 together define an annular, smooth, convexly curved sealing edge 14 surrounding a recess 16 within the cap 10 and electrode 12. The majority of the external peripheral surface of the cap 10 is convexly curved but is formed with a shallow annular concave

region 17 at its junction with the sealing edge 14. The sealing edge 14 merges smoothly with the inner surface of the recess 16 which has an annular undercut region 19. The region 19 is smooth and concavely curved.

The surface of the cap 10 presented away from the recess 16 includes a circular boss 18 with surrounding annular groove 20 having an annular sealing washer 21 therein formed of a suitable material such as latex. The boss 18 is hollow and is provided with an outer end wall 22 having a plurality (in this embodiment, three) of holes 24 therein which are spaced apart across the diameter thereof. The interior of the boss 18 opens into the recess 16 but is closed by a moulded resin insert 26 which is sealingly secured in position. The insert 26 has an axial passage 28 therethrough with cross-passages 30 extending radially therefrom to the outer periphery of the insert 26. Between the end wall 22 and the insert 26 there is defined a valve chamber 32 in which is disposed a valve disk 34 formed, in this embodiment, of a filled silicone rubber. The diameter of the disk 34 is about three quarters that of the chamber 32 and so is less than that of the chamber 32 but large enough to cover axial passage 28. That surface of the insert 26 which is presented to the valve chamber 32 defines a valve seat against which the valve disk 34 is sealingly engageable. The hollow boss 18 with holes 24 therethrough, the valve chamber 32 and the insert 26 with passages 28 and 30 therein together, in effect, define a passage in the body of the monitoring device, such passage communicating with the recess 16. The valve disk 34 and upper surface of the insert 26 together define in effect a means for sealing such passage.

Referring now to Fig. 4 of the drawings, the monitoring device further includes an elongate guide tube 36 of circular cross-section with a diameter and wall thickness

such that its lower end (as viewed in Fig. 4) is a close but detachable fit within the annular groove 20 in cap 10. Disposed within the guide tube 36 is a piston 38 fitted with an O-ring seal 40 which seals against the internal surface of the guide tube 36. The piston 38 is carried by a piston shaft 42 which extends throughout and projects from the upper end (not shown) of the guide tube 36. In this embodiment, the piston shaft is hollow, but it may be solid if desired. In this embodiment also, the guide tube 36 is formed of nylon to provide a degree of rigidity with some flexibility, and is slightly curved (not shown) over a distal end region thereof to facilitate introduction into the birth canal. The piston 38 is formed of PVC, whilst the piston shaft 42 is formed of low density polyethylene and is more flexible than the guide tube 36. This is to make the assembly easy to handle. The wall of the guide tube 36 has a vent hole 44 therethrough at a location which is spaced from the lower end of the guide tube 36 by a distance sufficient to give the required degree of suction within the recess 16 as will be described hereinafter.

In use, the part of the monitoring device described and illustrated with reference to Figs.1 to 3 above is engaged with and supported by the guide tube 36 with the lower (or distal) end of the latter frictionally engaged in the annular groove 20 and sealed against the washer 21 therein. Temporary securing of the guide tube 36 to the cap 10 is further assisted by clipping the electrode leads 13 temporarily in a suitably shaped retaining notch 52 in a handle 54 at the proximal end of the piston rod 42. If desired, an axial recess (not shown) may be provided in the outer surface of the guide tube 36 to receive the leads 13, or a separate tube (also not shown) may be provided for containing the leads.

The guide tube 36 can then be used to introduce the cap 10 into the birth canal so as to bring the sealing edge 14 directly into contact with the tissue 50 (see Fig. 2) of the presenting part of the fetus, which will normally be the fetal head. The leads 13 are then disengaged from the notch 52 and, whilst holding the cap 10 in position using the tube 36, and with the piston 38 in a forward position (as shown in Fig. 4), the piston shaft 42 is then pulled back using the handle 54. This exerts a reduced pressure within the lower end of the guide tube 36 which causes the valve disk 34 to move from its rest position (Fig. 5a) into an opened position (Fig. 5b) which allows a reduced pressure to be applied to the chamber 16. This causes the fetal tissue 50 to be drawn into the recess 16 and to seal effectively against the sealing edge 14 as shown in Fig. 2 where it will be seen that the fetal tissue 50 is pulled partially up into the recess 16 to enter the concave region 19 thereof. Undue stretching of the fetal tissue 50 and complete filling of the recess 16 is prevented by reason of engagement of the tissue against the lower surface of the insert 26 (as viewed in Fig. 2). Once the fetal tissue 50 has been partially drawn into the recess 16, an oedematous response (swelling with fluid) occurs and this fills the cup to the required extent. The cross passages 30 allow a negative pressure to be distributed over a large area of fetal tisssue 50 and ensures that a good electrical contact is maintained with the electrode 12.

Once the O-ring seal 40 has travelled along the guide tube 36 past the vent hole 44, the reduced pressure in the lower end of the guide tube 36 is relieved. The differential pressure then acting across the valve disk 34 causes it to move promptly into its sealing position against the insert 26 (as shown in Fig. 5c). Closure of the valve serves to seal the reduced pressure within the recess 16 so as to maintain the cap 10 and electrode 12

in close contact with the fetal tissue 50. This enables the requires signals to be obtained via the electrode 12 and the lead connected thereto. The manner in which the signals are taken and analysed are per se known and therefore need not be described herein. It will be appreciated that, once sealing has taken place, the guide tube 36 can be completely removed and so does not present any further obstruction or impedance to the person responsible for delivery. Once delivery has taken place, the cap 10 can be removed by carefully pressing a small region of the fetal tissue 50 away from the sealing edge 12 to relieve the reduced pressure within the recess 16. It will be appreciated that the provision of the holes 24 across the diameter of the wall 20 of the boss 18 ensures that the valve disk 34 can never completely seal the holes 24 whilst suction is being applied (as shown in Fig. 5b).

The use of the electrode 12 to form part of the sealing edge 14 ensures that there is always an effective contact maintained between the electrode 12 and the fetal tissue 50 whilst the device is in use.

In the above described embodiment, the monitoring device is used for CTG purposes. However, it will be appreciated that the electrode 12 can be used mutatis mutandis for other purposes if desired. It will further be appreciated that more than one electrode may be provided and that each of such electrodes may have portioned defining part of the sealing edge 14. Alternatively, further electrodes may be provided externally of the cap 10. Furthermore, the cap 10 may also be used to support any other type of sensor, for example, for pH or oxygen monitoring simply by providing appropriate sensors within the recess 16 or outside the cap 10.

In the above-described embodiments, it will be noted that the distal end of the guide tube 36 engages in the groove 20 and extends rearwardly substantially axially of the cap 10. In some cases, particularly during the early labour stage, it can be difficult to bring the cap 10 flush with the fetal head. To overcome this problem, the guide tube 36 is connected with the cap 10 through the intermediary of a small adapter body which fits over part of the rear of the cap 10 and has an internal sleeve which loosely engages in the groove 20. The adapter body has an external, rearwardly presented recess by means of which finger pressure can be applied to ensure flush engagement of the cap 10 with the fetal tissue and to facilitate steadying of the cap 10 during fitting. The adapter body also has a passage therein which communicates with the holes 30 and which extends rearwardly and laterally of the adapter body to pass through an external circular boss which extends rearwardly at an angle of about 45 degrees relative to the axis of the cap 10. The guide tube 36 frictionally engages over this boss and so extends in a direction which more easily permits a finger to be inserted to press the cap 10 into position without bending the guide tube 36 during fitting of the cap 10. Finger pressure on the adapter body can be continued in order to hold the cap 10 in the correct position whilst reduced pressure is being applied.

CLAIMS

1. A monitoring device comprising a body (10), a recess (16) within the body (10), a sealing edge (14) surrounding the recess (16) and adapted to engage sealingly against a surface (50) to which the device is to be secured in use, a passage (24, 32, 28, 30) in the body (10) communicating with the recess (16), at least one monitoring element (12) carried by the body (10), and means (36, 38, 40, 42) for applying a reduced pressure to the passage (24, 32, 28, 30), and thereby to the recess (16), so as to secure the body (10) in use to the surface with said at least one monitoring element (12) in a predetermined position relative to said surface, characterized in that the means (36, 38, 40, 42) for applying reduced pressure is detachable from the body (10), and in that means (26, 34) are provided for sealing said passage so as to enable reduced pressure to be maintained in the recess (16) in use after detachment of the reduced pressure applying means (36, 38, 40, 42).

2. A device as claimed in claim 1, wherein the means (36, 38, 40, 42) for applying reduced pressure comprises a piston (38, 40) and suction tube (36) device, the suction tube (36) being detachably connected with the passage (24, 32, 28, 30).

3. A device as claimed in claim 2, wherein the suction tube (36) comprises an elongated tube having a vent orifice (44) intermediate its ends.

4. A device as claimed in any preceding claim, wherein valve means (26, 34) provide the means for sealing the passage.

5. A device as claimed in claim 4, wherein the valve means (26, 34) includes a pressure-responsive valve

closure member (34) adapted to close when a greater negative pressure exists in the recess (16) than in the reduced pressure applying means.

6. A device as claimed in any preceding claim, wherein the body (10) takes the form of a suction cap.

7. A device as claimed in any preceding claim, wherein said at least one monitoring element (12) is provided in the region of the sealing edge (14).

8. A device as claimed in claim 6, wherein said at least one monitoring element (12) defines at least part of the sealing edge (14).

9. A device as claimed in any preceding claim, wherein the body is adapted to seal against a flexible surface (50) and abutment means (26) are provided within the recess (16) for limiting deformation of the surface into the recess (16).

FIG 1

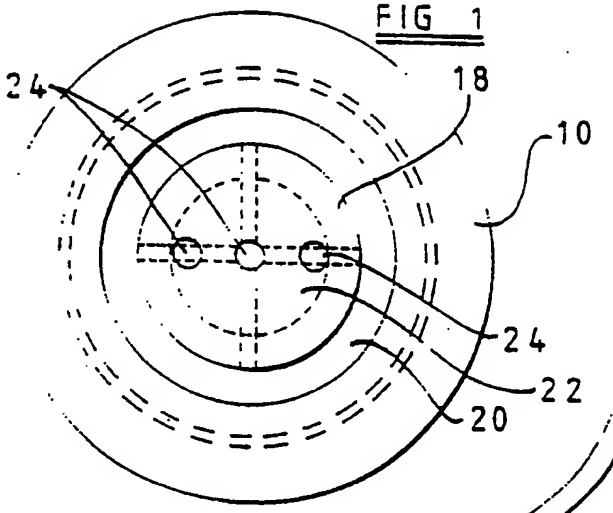

FIG 2

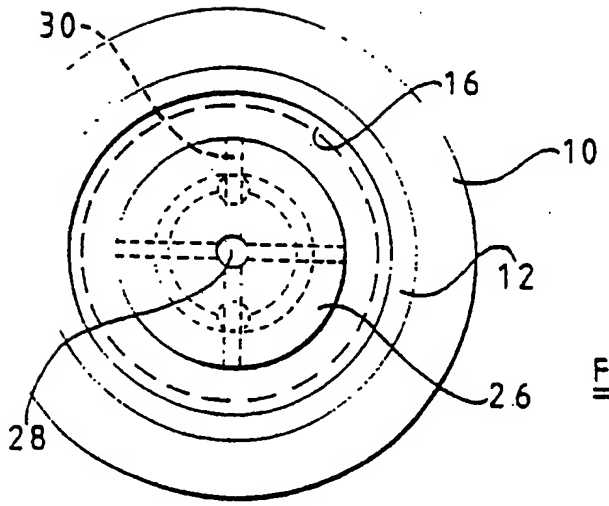

FIG 3

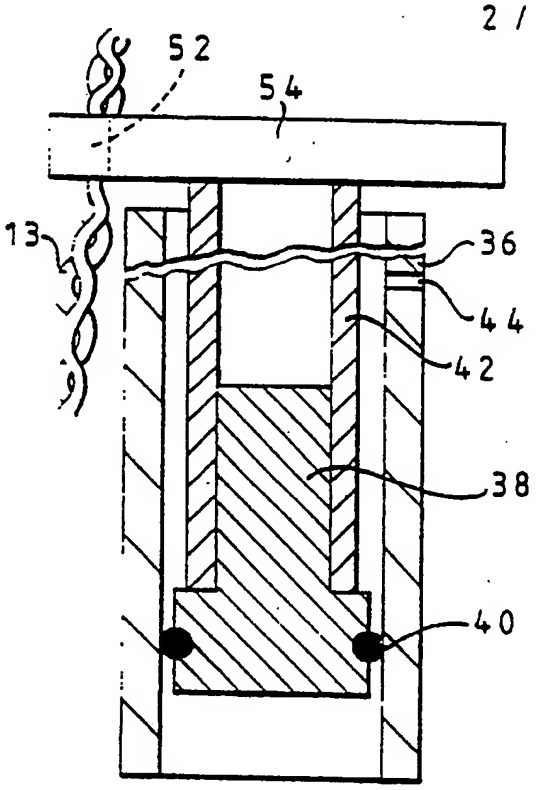

FIG 4

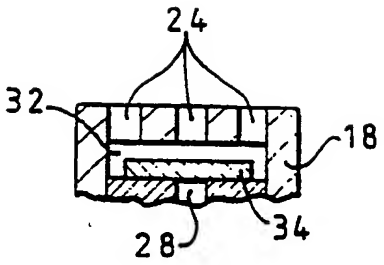

FIG 5a

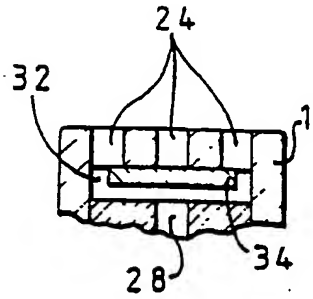

FIG 5b

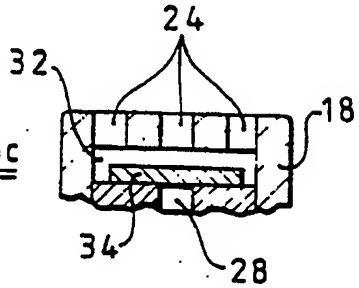

FIG 5c

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 91/01660

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B5/0448

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B ; A61N

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
A	DE,U,8 907 755 (METRONIC ELECTRONIC G.M.B.H.) 14 September 1989 see page 4, line 9 - page 6, line 5	1,4-7,9
A	FR,A,1 139 191 (S.A.M.P.) 26 June 1957 see page 1, column 2, line 26 - line 36 see figure 1	1,4-6,9
A	US,A,4 217 908 (P.J. STAVER) 19 August 1980 see column 2, line 35 - column 3, line 62	1,6,7,9
A	US,A,2 580 628 (W.W. WELSH) 1 January 1952 see column 2, line 54 - column 3, line 57 see figure 2	1,2,6-8

* Special categories of cited documents : [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13 DECEMBER 1991	29. 01. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	RIEB K.D.

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-U-8907755	14-09-89	None	
FR-A-1139191		BE-A- 534911	
US-A-4217908	19-08-80	None	
US-A-2580628		None	